

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61K 7/42	A1	(11) International Publication Number: WO 95/19161 (43) International Publication Date: 20 July 1995 (20.07.95)
(21) International Application Number: PCT/US94/13422 (22) International Filing Date: 16 November 1994 (16.11.94) (30) Priority Data: 08/154,584 18 November 1993 (18.11.93) US (60) Parent Application or Grant (63) Related by Continuation US Not furnished (CIP) Filed on Not furnished (71)(72) Applicant and Inventor: STEWART, Ernest, G. [US/US]; 101 West Club Drive, Thomasville, GA 31792 (US). (74) Agent: CONA, Franklin, J.; P.O. Box 10394, Bradenton, FL 34282 (US).		(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, LV, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: IMPROVED WATER RESISTANT SUNSCREEN PROTECTION AND INSECT REPELLENT COMPOUND (57) Abstract <p>An improved waterproof sunscreen protection and insect repellent combination compound having an SPF factor of 15 and further having an unexpected unusually long efficacy period when used in rainy conditions and prolonged periods of high humidity as in tropical and sub-tropical rain forests or the like, and in underwater conditions as in swimming. The compound forms a lotion that is easy to store. The lotion can be applied to the skin of a person with little or no training. No special precautions are required by the person when applying the lotion. The compound has a sweet taste when applied to the lips and is pleasantly scented. The compound forms a thin waterproof film on the skin, but is non-greasy to the touch. The lotion is easily removed by scrubbing with soap and water. The sunscreen component being about between 10 % to 20 % by weight, the insect repellent compound being about between 10 % to 30 % by weight, the waterproofing agent being about between 2 % to 4 % by weight, and the water based solvent being about between 27 % to 37 % by weight.</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

TITLE OF INVENTION**IMPROVED WATER RESISTANT SUNSCREEN PROTECTION &
INSECT REPELLENT COMPOUND****BACKGROUND OF THE INVENTION****Field of the Invention**

This invention relates to a synergistic compound for sunscreen protection and insect repellent compound, and in particular an improved water resistant combination sunscreen protection and insect repellent compound. The compound is nongreasy, pleasant smelling, and sweet tasting with an approximate SPF factor of 15. Although the compound is highly water resistant, it is easily removed with soap and water and scrubbing.

Description of the Background Art

Insect borne diseases are a major non-battle injury threat to the military. Seven of the top 11 diseases that reduce military effectiveness are transmitted by insects. It is imperative for peak military operational efficiency that an acceptable insect repellent be produced to reduce the disease threat and to provide personal protection from insect borne diseases. The insect repellent compound must also meet the unique requirements necessary for personal protection of the armed forces. When considering the broad spectrum of use, the repellent should be long lasting and acceptable to the user. Also, the military spends long periods of time outdoors and

accordingly, an acceptable sunscreen protectant/insect repellent combination compound for use by field military personnel is highly desirable, particularly if it is compatible with other military materials, such as clothing and weapons. In other words, the compound should not have a negative effect on uniforms or the use and operation of weapons.

The military services have not developed a satisfactory sunscreen protectant/insect repellent compound that meet their unique operating needs.

A second major need exists for people who live and work and play in the outdoors. They have protected themselves from insects for years by using insect repellent compounds. Likewise, people who live and play and work outdoors have used suntan compounds to accelerate the darkening of the exposed skin. Only recently the knowledge of the adverse effects of the sun's ultra violet rays causing skin cancer has caused people to switch from suntan lotions to suncreening lotions that provide protection from the sun. Those lotions are measured on a scale of increasing protection from 1 to 100. The scale is called the "SPF" or Sun Protection Factor. An accepted standard for measuring protection against sunburn is the Sunscreen Protection Factor (SPF). The SPF factor allows the consumer to determine the degree of sunburn that one is willing to accept for a given period of time in the direct rays of the sun's ultra violet rays.

Many civilian products have become commercially available in the recent past that combine sunscreen protection lotions and insect repellent lotions in one package. These products, for many reasons, are not completely satisfactory. Among the reasons why they are not satisfactory are:

First, the insect repellent compounds available are greasy, have a foul odor, and are usually effective for short periods and require the person to continuously apply the lotion to maintain the desired degree of insect repellency on the skin. In many cases, as for example, in a duck blind this is very inconvenient because the person can not repeatedly apply the insect repellent lotion and maintain perfect stillness in the duck blind.

Second, many combination insect repellent and sunscreen protection compounds are easily removed with water. This is a particular problem in the summertime when the person sweats. The effectiveness of the insect repellent and sunscreen protection lotion is dramatically reduced due to sweat removing the compound from the skin.

Third, most insect repellent compounds are oily and offensive to the olfactory systems of the wearer as well as people around the wearer. Also, the heaviness in the material is an impediment to the function of the sweat glands and could cause discomfort to the wearer.

Fourth, the preparations commercially available today are not truly cosmetic in that they do not enhance the appearance and the texture of the skin.

Fifth, most sunscreen protectant compounds have a bitter taste when applied to skin around the lips.

Patent 1,471,344 issued to Loudin discloses a insect repellent composition which mixes equal parts of PHENYL SALICYLATE and camphor.

Patent 3,186,912 issued to Beamer discloses a cosmetic emulsion having suncreening and insect repellent properties.

Patent 4,529,598 issued to Wong discloses an insect repellent compound which can be used as a sole active component or in an admixture with other compounds having a different utility. The invention further discloses the compound may be incorporated into a cream, lotion, powder or a suntan oil.

Patent 2,170,185 issued to Carpenter discloses a suntan cream having methyl anthranilate which is a methyl ester of anthranilic acid.

Patent 4,434,154 issued to McShane discloses a tanning and screening compound that is highly stable after prolonged storage. The compound is useful even after prolonged storage

for shielding human skin from the harmful ultra violet rays of the sun.

Patent 4,701,321 issued to Bernstein discloses a liquid detergent with a sunscreen agent selected from the aminobenzoic acid family the other components of the composition being a preservative, a non-ionic detergent, an amphoteric detergent, or a mixture thereof in a aqueous vehicle.

Patent 4,820,508 issued to Wortzman discloses a skin protective composition for topical application to protect human skin from infrared radiation. The invention contains titanium dioxide and mica or coated mica as its' principal active reagents.

Patent 4,756,905 issued to Melnik discloses a composition for repelling insects and camouflaging the human skin. The insect repellent, N or N-DIETHYL-M-TOLUAMIDE and a camouflage pigment is combined along with an emulsifier to allow a single application to serve both functions.

Patent 3,590,118 issued to Conrady, et al discloses a long lasting insect repellent film for skin application. The active chemical agents are dissolved in interpolymer resins to provide a slow release system for the active chemical agents when spread and dried as a film on a human being. The coating can be applied by spraying or spreading and is easily removable with a soapy water solution.

None of these previous efforts, however, provide the benefits intended with the present invention. Additionally, prior techniques do not suggest, the present inventive combination of component elements as disclosed and claimed herein. The present invention achieves its intended purposes, objectives and advantages over the prior art devices through a new, useful and unobvious combination of component elements, which is simple to use, with the utilization of a minimum number of functioning ingredients, at a reasonable cost to manufacture, test, package and by employing only readily available materials.

Accordingly, it is an object of the invention to provide a combination sunscreen protection and insect repellent product that meet the broad spectrum of use for military personnel.

It is an object of the invention to provide a combination sunscreen protection and insect repellent product that contributes to the effectiveness of the military by reducing insect borne disease among military personnel.

It is another object of the invention to provide a combination sunscreen protection and insect repellent product that is resistant to breakdown by water, but is readily removed by soap and water and mild scrubbing.

It is a further object of the invention to provide a combination sunscreen protection and insect repellent product

that is not greasy to the touch, pleasant smelling to the wearer, sweet tasting when applied to skin close to the lips, and nonoffensive to those people around the wearer.

It is a still further object of the invention to provide a combination sunscreen protection and insect repellent product that does not impede the natural function of the wearers' sweat glands.

It is a further important object of the invention to provide a combination sunscreen protection and insect repellent product that enhances the appearance and feel of the wearers' skin.

It is a final important object of the invention to provide a combination sunscreen protection and insect repellent product that is long lasting and does not require frequent reapplication to maintain its effectiveness.

Although there have been many inventions related to sunscreen protection and insect repellent compounds, none of the inventions have become sufficiently effective, low cost and reliable enough to become commonly used. The present invention meets the requirements of long lasting efficacy under extreme environmental conditions, low initial cost, water resistant, non-greasy, sweet tasting, ease of application, pleasing to the olfactory senses, and minimal amount of instruction to successfully practice and use the invention.

The foregoing has outlined some of the more pertinent objects of the invention. These objects should be construed to be merely illustrative of some of the more prominent features and applications of the intended invention. Many other beneficial results can be obtained by applying the disclosed invention in a different manner or modifying the invention within the scope of the disclosure. Accordingly, other objects and a fuller understanding of the invention may be had by referring to the summary of the invention and the detailed description of the preferred embodiments in addition to the scope of the invention defined by the claims.

SUMMARY OF THE INVENTION

For the purpose of summarizing the invention, the invention may be incorporated into a synergistic waterproof sunscreen protection and insect repellent compound having an extremely long efficacy period when used in rainy conditions and prolonged periods of high humidity as in tropical and sub-tropical rain forests, and even underwater. The compound comprises a sunscreen constituent constituting about between 10% to 20% by weight of the compound, an insect repellent constituent constituting about between 10% to 30% by weight of the compound, a waterproofing constituent of about between 2% to 4% by weight, a plurality of ingredients contributing the synergistically long efficacy attribute, and the balance being composed of a water based solvent comprising about between 27% to 37% by weight of the compound.

The compound forms a lotion that is easy to store. The lotion can be applied to the skin of a person with little or no training. No special precautions are required by the person when applying the lotion. When applied, a thin film is formed on the skin that is non-greasy to the touch and resists water, yet is readily removed by soap and water and scrubbing.

The resultant compound has an extremely long efficacy period even when subjected to extreme environmental conditions of high humidity, and even when the wearer is underwater. Further, the compound was tested exhaustively under strict laboratory and

field conditions using the appropriate protocols that are approved by the US Army Medical Material Development Activity.

The foregoing has outlined rather broadly the more pertinent and important features of the present invention in order that the detailed description of the invention that follows may be better understood so that the present contribution to the art can be more fully appreciated. Additional features of the invention will be described hereinafter which form the subject of the claims of the invention. It should be appreciated by those skilled in the art that the conception and the specific embodiments disclosed may be readily utilized as a basis for modifying or designing other structures for carrying out the same purposes of the present invention. It should also be realized by those skilled in the art that such equivalent structures do not depart from the spirit and scope of the invention as set forth in the appended claims.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention, Example 1, is prepared using the components in Phases A, B, C, D, E and F respectively. The resulting compound that is produced in accordance with the present invention has the desired characteristics of providing a waterproof nongreasy, pleasant smelling, insect repellent and a sweet tasting sunscreen protectant with an approximate SPF of 15. The compound forms a lotion that is easy to store. The lotion can be applied to the skin of a person with little or no training. No special precautions are required by the person when applying the lotion. Further, the resultant compound has the synergistic attribute of an extremely long efficacy period when used in rainy conditions and prolonged periods of high humidity as in tropical and sub-tropical rain forests or the like, or when the wearer is underwater. The compound forms a thin waterproof film on the skin which resists water, yet is readily removed by soap and water and scrubbing.

The compound was evaluated under appropriate protocols for measuring the efficacy of sunscreen formulations and insect repellent formulations against mosquitos. Cage tests were conducted at Walter Reed Army Hospital. Then, the compound was tested under strict field conditions using appropriate protocols that are approved by the US Army Medical Material Development Activity. The field tests were conducted at the US Army testing facilities in Alaska, Thailand, and South America.

Immersion tests were conducted to determine the waterproofing effectiveness of the compound. Five test subjects were immersed in a whirlpool for a total of eighty (80) minutes. The initial SPF factor prior to immersion was 16.1. Measurements were taken at 20 minute intervals on all 5 test subjects. The interim SPF factor and final SPF factor was 16.1 in all cases. Additional tests are planned with longer durations to confirm the original results and to probe for the upper limit of the waterproofing effectiveness of the invention.

The practice of the invention results in a composition as shown below in Example I, with the ingredients being representative of their constituent percentages by weight percent.

EXAMPLE I

<u>PHASE A</u>	<u>WEIGHT %</u>
Deionized Water	32.53
Propylene Glycol	2.50
Carbopol 940 (2% Soln)	5.00
Pemulen TR1	15.00
Seamollient	1.00
Tetrasodium EDTA	0.10
<u>PHASE B</u>	
N,N-diethyl-M-toluamide (Deet)	17.00
Cetearyl Alcohol (Crodocol CS-50)	3.50
Octyl Methoxycinnamate (Neoheliopan AV)	7.50
Octyl Salicate (Neoheliopan OS)	5.00

Peg 40 Sterate (MYRJ 52S)	0.15
Sunscreen (Benzophenone-3)	6.00
Tricontonyl PVP (Ganex WP-660)	3.00
Vitamin E Acetate	0.25

PHASE C

Triethanolamine 99%	0.11
---------------------	------

PHASE D

Citronella Java	0.01
Fragrance MF 3871	0.25

PHASE E

Sodium Saccharin	0.10
------------------	------

PHASE F

Germaben II	1.00
-------------	------

The mixing is done in a conventional manner and the ingredients in each phase are mixed in the sequence described hereinbelow. The choice of the particular material used dictates the mixing time and temperature change rates.

The invention is practiced by first mixing water and propylene glycol for forming an initial mixture and heating the initial mixture to 75° C with propeller agitation in a stainless steel kettle large enough to hold the entire batch and slowly sifting in carbopol and then Pemulen TR1. Then, seamollient and disodium EDTA are added uniformly to form a first interim mixture. The first interim mixture is mixed while maintaining the temperature in the kettle at 75° C for 30 minutes.

Next, N,N-diethyl-M-toluamide (deet), cetearyl alcohol, octyl methoxycinnamate, octyl salicilate, peg-40 stearate (MYRJ 52S), oxybenzone (sunscreen), tricontonyl PVP (Ganex WP-660), and vitamin E acetate are combined in a second initial mixture with slow agitation in a second stainless steel kettle and heated to 85° C. The ingredients in the second kettle are mixed for 30 minutes while maintaining the temperature. After 30 minutes has elapsed, the second initial mixture in the second kettle is added to the interim mixture in the first kettle and a second interim mixture is formed. The second interim mixture is mixed for 30 minutes. Then, triethanolamine is added to the second interim mixture in the first kettle using a slow sidesweep agitation to produce a third interim mixture. The third interim mixture in the first kettle is mixed for 30

minutes while maintaining the temperature at 75° C. Then, the third interim mixture in the first kettle is cooled to 45° C while stirring slowly. Citronella, fragrance, saccharin and germaben II are then slowly added to the third interim mixture in the first kettle to produce a resultant mixture.

The resultant mixture in the first kettle is mixed for 20 minutes to provide uniformity and then the resultant mixture is passed through a Gifford-Wood colloid mill with a narrow setting for providing a small particle size. The resultant mixture is recirculated in the first kettle until homogeneity is achieved and at this point, the resultant mixture is ready for packaging.

The composition of the sunscreen component comprises from about between 10% to 20% by weight of the composition. The composition of the insect repellent component comprises from about between 10% to 30% by weight of the composition. The composition of the waterproofing component is about between 2% to 4% by weight. The composition of the water based filler comprises from about between 27% to 37% by weight of the composition. The balance of the composition comprises agents commonly used as ingredients to produce qualities such as fragrance, color and sweet taste .

When a person applies the compound outlined in Example 1 to the exposed parts of the body, according to the method disclosed herewith, a thin film forms on the skin that provides a non-

greasy, pleasant smelling insect repellent and a sweet tasting sunscreen protectant. The compound has the unexpected property of extremely long efficacy even when subjected to extreme temperature and humidity, and even when the exposed body parts are underwater for extended periods of time. The synergistic result of combining Pemulen TR1, MYRJ 52S (Peg 40 Sterate), and Ganex WP-660 (Tricontonyl PVP) in the quantities disclosed in Example 1, and preparing the compound according to the steps disclosed herein provide the invention with unexpected superior insect repellent and sunscreen properties.

Pemulen TR1 is a known emulsifier/stabilizer. The product is made by the B. F. Goodrich company in Akron, Ohio. Predominantly, it is known for its emulsion/stabilization quality. Typically, Pemulen TR1 is used in perfumes and hair glossing and elegant skin care moisturizer applications.

MYRJ 52S is a non-ionic oil and water emulsifier. It is manufactured by the ICI Corporation in Wilmington, Delaware. Primarily, MYRJ 52S is known for its emulsification qualities. Typically, MYRJ 52S is used for general skin formulations including facial lotions and skin moisturizers and the like.

The preferred waterproofing component is Tricontonyl PVP (GANEX WP660). The operating range of the waterproofing component is about between 2% to 4% by weight, preferably 3%. The component provides a barrier between the sunscreen ingredient and the insect repellent ingredient which prevents the Deet from

dissolving the Benzophenone-3. This is due to the unexpected result that when the water-proofing component is added, the vapor pressure is lowered significantly and accordingly increases the efficacy of the insect repellent over the entire operating range of the compound as claimed and disclosed.

Ganex WP660 is a film-forming waterproof agent manufactured by the ISP Corporation (International Specialty Products) of Wayne, New Jersey. Primarily, it is used for quality waterproofing sunscreen formulations.

The combination of MYRJ 52S, Pemulen TR1, Ganex WP660, Benzophenone-3 (sunscreen) and N, N-Diethyl-M-Toluamide (DEET) would not normally be expected to form an emulsion when combined. However, by combining them in the ratios disclosed, a stable emulsion is formed. This emulsion when rubbed onto the skin "breaks down" as the Pemulen is precipitated by the salt on the skin and the emulsion breaks. There is now insufficient emulsifier left on the skin to wash off when sweating or swimming. Additionally, the Ganex WP660 combines with the DEET and the sunscreen to form a uniform thick sunscreen film which is waterproof. The increased thickness of the film allows for enhanced SPF performance since the optical path length of the UV radiation have now increased and thus the sunscreen absorbs the UV more efficiently.

The prior art does not reveal nor even suggest a motivation for combining the above cited ingredients. The inventor

experimented with various compounds hoping to develop the invention. It was only after numerous failed attempts, that the invention was finally achieved. Cage tests were conducted at W. Reed U. S. Army hospital and were followed by exhaustive trials under actual field conditions with extreme temperature and humidity. The field trials were conducted by the U. S. Army Medical Material Development Activity, Office of Research and Technology Applications, at their test facilities in Alaska, Thailand, and South America. The results confirmed the disclosed and claimed synergistic increase in efficacy beyond dispute. The written results of the cage tests and field trials are hereby submitted and incorporated by reference as part of the detailed description of the preferred embodiment. The written results include:

1. Memorandum dated May 7, 1993 from the staff director of the Medical Standardization Board at Ft. Detrick, Maryland from L. Gober, MD, Colonel, MC, USA to Major Gupta, Department of Entomology at Walter Reed Army Institute of Research in Washington, DC. The subject of the memorandum is a request to test commercially available combinations of insect repellent and sunscreen that comprises the instant invention.

Paragraph one of the instant memorandum indicates the urgent requirement for this item to be placed in the medical packet, individual survivor kit of the United States Army. Further, paragraph one indicates that the insect repellent and sunscreen compound that is currently used by the US Army is no longer adequate. Accordingly, the instant invention disclosed in

applicant's invention is addressing a long felt need, and in particular, a need of the US military.

Your attention is directed to paragraph two in the memorandum indicating that the sun protection factor of the instant invention (SPF) is 23 which far exceeds any product submitted to the Defense Medical Standardization Board to date.

2. A second memorandum from the Walter Reed Army Institute of Research dated January 7, 1994 disclosing the initial testing of the instant invention. The tests were conducted by the Defense Medical Standardization Board at Walter Reed Army Hospital. The data indicates that the instant invention was efficacious beyond eight hours. This means that the treated arm in the cage did not receive a mosquito bite while the untreated arm in the cage received numerous mosquito bites during seven tests. The actual data is submitted herewith as page 2 of the instant memorandum.

Paragraph two indicates the test methodology used at the Walter Reed Institute of Research. Further, the last sentence that "the amount of estimated protection may be an underestimate for the 10 to 12 hour intervals after application since the number of biting controls (untreated) would be much higher." In effect, the US Army Division of Communicable Disease and Immunology has never had a combination sunscreen and insect repellent product that retained its waterproofing efficacy for this extremely long period of time. As disclosed and claimed

in the instant application, applicant's invention is well beyond the envelope of all known efficacy for insect repellency.

Paragraph three of the second memo indicates that new testing protocols will have to be developed by the Department of Communicable Disease and Immunology in order to fully test the efficacy of the instant invention.

3. A memorandum for the Chief of the Department of Entomology, Division of Communicable Disease and Immunology, Walter Reed Army Institute of Research, Washington, DC. The subject of the third document dated May 11, 1994 is a proposal to conduct field tests of the instant invention.

Paragraphs one and two summarize the test results that have been performed on the instant invention to date at the Walter Reed Army Hospital in Washington, DC. Paragraph two restates the conclusion that the repellents have been effective for up to 10 to 12 hours on male subjects. The instant memorandum further indicates that tests will have to be conducted to determine the differences in duration and the requirements for the application of the instant invention for both males and females.

Paragraph three proposes to evaluate the instant invention in the field in Australia, Peru, Florida and Brazil. The purpose of the field trials is to evaluate the instant invention against a wide variety of species of different

Malaria carriers and certain sand fleas and also nuisance biting flies. It is also noteworthy that the concentration of deet is 20% in the instant invention. This concentration is the lowest effective concentration of deet available in any insect repellent compound. New York State has outlawed any compound with a concentration of Deet higher than 30%.

Paragraph four is directed to the cost of conducting the field trials overseas.

Paragraph five indicates that the field data obtained would be provided to the inventors and published in scientific journals, after review by the inventors.

Paragraph six indicates that an amendment to the existing agreement between the inventors and the Walter Reed Army Immunization and Research Bureau will be performed to authorize the studies and a statement of work for the field trials.

In summary, the field tests further reinforce the inventor's claim that the efficacy of the instant invention is beyond the envelope in terms of utility and efficacy when evaluated against any prior product by the US Army Department of Entomology, Division of Communicable Disease and Immunology. Specifically, the test protocols currently used heretofore were inadequate to fully measure the scope of the efficacy of the instant invention. The instant invention has exceeded all known expected results in the tests conducted to date by the Department of Entomology, Division of Communicable Disease and

Immunology at the Walter Reed Army Institute of Research. The field trials in Australia, Peru, Florida and Brazil will further document the unparalleled efficacy and the unexpected results of the instant invention. Those field trial results will be made available to the PCT immediately upon receipt from the authorities at the Walter Reed Army Institute.

The underwater tests were conducted in a whirlpool with a person having the invention applied to their skin. There were a total of five test subjects in the whirlpool with the invention applied on their skin. The subjects were immersed in the whirlpool which was under extreme agitation and were removed from the whirlpool at 20 minute intervals to measure the SPF factor. Test results show that the SPF factor was 16.1 upon initial immersion and 16.1 after 80 minutes or four measurement observations. The SPF factor of the compound showed absolutely no degradation whatsoever. The immersion tests were terminated at that time as lack of degradation indicated that the SPF factor of the invention would last well beyond the target spectrum of three hours. The immersion tests conducted by the US Army Office of Research and Technology Application Personnel at Walter Reed Army Hospital in Washington, DC, indicates that the SPF factor is unaffected after exposure underwater.

In a less preferred embodiment a petroleum wax is used to encapsulate and isolate the Deet from the sunscreen. This version of the compound provides dramatic improvements to the

efficacy of the compound by allowing the water-proofing agent to maintain its efficacy in spite of the tendency of Deet to dissolve water-proofing agents, as is well known.

Alternatively the compound can be incorporated into a third less preferred embodiment forming a solid product using non-cosmetic resins such as polystyrene, neophrine, paints, plastic, silicones, and fiberglass, preferably polystyrene.

The third less preferred compound is produced by dissolving the non-cosmetic resin into the liquid mixture and then adding back enough resin to form a solid compound. Then, the compound is allowed to cure to a completely solid state and further, is ground into a fine powder. The compound then can be incorporated in a familiar aerosol spray version to spray on clothing to impregnate the cloth with the insect repellent attributes or can be formed into commonly found deodorant sticks. Also, it can be re-introduced into a separate liquid, such as paint or the like. Alternatively, the fine powder can be introduced into a separate solid material such as fiberboard or fiberglass to provide insect proofing to homes and residences. In effect, the compound can be used to provide long term insect proofing in the residential construction industry by incorporating the compound into common building materials such as paint and wallboard and insulation materials. An even less preferred embodiment incorporates the use of the compound by entrapping the compound in a microsphere product

which are known in the art, for example, microsphere 5640 manufactured by Dow Chemical Co.

Finally, the compound can be separated into its two primary constituents for providing sunscreen protection and insect repellency. In this manner, the compound can be applied to the skin in a two-step process with no degradation of efficacy. Further, it is immaterial whether the sunscreen product is applied first to the skin and the insect repellent product applied thereafter, or if the process is reversed. That is, the insect repellent product can be applied to the skin first and then the sunscreen can be applied over the insect repellent product. In either case cited above, the compound maintains its sunscreen protection factor (SPF) levels throughout the observed test data.

The present disclosure includes that contained in the appended claims, as well as that of the foregoing description. Although this invention has been described in its preferred form with a certain degree of particularity, it is understood that the present disclosure of the preferred form has been made only by way of example and that numerous changes in the details of structures and the combination of individual ingredients may be resorted to without departing from the spirit and scope of the invention.

Now that the invention has been described,

Code 173

7 May 1993

From: Staff Director
To: Major Raj K. Gupta, Department of Entomology, Walter Reed Army
Institute of Research, Washing, DC 20307-5100

Via: (1) Research Area Director, U. S. Army Research and Development
Command, ATTN: SGRG-PLA, Ft. Detrick, Frederick, MD 21702-5010
(2) Director, Walter Reed Army Institute of Research,
Washington, DC 20307-5100

Subj: REQUEST FOR TESTING OF COMMERCIALY AVAILABLE COMBINATION INSECT
REPELLENT AND SUNSCREEN


Ref: (a) DMSB ltr Code 173 dtd 29 Jul 92

Encl: (1) DMSB Item Review Report Ser 9-0174 dtd 23 Feb 89

1. The current source for a combination insect repellent and sunscreen, NSN 6505-01-288-2188, is no longer adequate or available. There remains an urgent requirement for this item to be placed in the Medical Packet, Individual Survival Kit, NSN 6545-00-231-9421.

2. It has come to my attention that Amon-Re', Inc., P. O. Box 1657, Thomasville, GA 31799, Phone 1-800-344-8262, has a waterproof insect repellent sunscreen product. The ability of this product to be waterproof with an SPF of 23, far exceeds any product submitted to date.

3. Request you conduct subject testing, first requested in reference (a), as soon as possible to allow for the rapid standardization of a suitable substitute to the terminal NSN item. The item's essential characteristics are contained in enclosure (1). POC is J. C. Sherman at (301) 619-7107 or DSN 343-7107.


LOMMAN E. GOBER, MD
Colonel, MC, USA

7 January 1994

SGRD-UWF-B

MEMORANDUM FOR

Chief, Department of Entomology, Division of Communicable
Disease and Immunology, Walter Reed Army Institute of
Research, Washing, DC 20307-5100.

SUBJECT: Evaluation of Deet Arthropod Repellent Sunscreen
SPF-23

1. We evaluated a "Deet Arthropod Repellent Sunscreen (SPF-23)" formulation (provided by Amon-Re, Inc., P. O. Box 1657, Thomasville, GA 31799, Phone 1-800-344-8262, against ~~and~~ ~~and~~ ~~egypti~~ to determine duration of efficacy in the laboratory. Because the tested formulation did provide protection in the laboratory for 10-12 hr, the tests were stopped after 7 replicates.

2. Methods: Ten mosquitoes each per cage were exposed to a treated (.1ml sunscreen + Deet) and untreated forearm of a human volunteer. The test was continued for 5 minutes for each cage unless 3 bites were received by mosquitoes in that cage. For all replicates (total = 7), the test cage was removed after 3 bites were received on that treated or untreated arm, i.e., when 3 bites were received on the untreated arm, that cage was removed. Therefore, the amount of estimated protection may be an underestimate for the 10 to 12 hr intervals after application since the number of biting controls (untreated) would be much higher.

3. New testing protocols need to be updated since there has never been a waterproof insect repellent submitted for testing, much less a combination product.

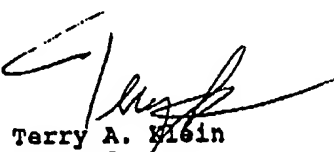
SUBJECT: Evaluation of Deet Arthropod Repellent Sunscreen
SPF-23

4. Data:

Replicate	TREAT Hour/Bites				UNTREAT Hour/Bites			
	2	4	6	8	2	4	6	8
1	0	0	0	0	3	3	3	3
2	0	0	0	0	3	3	3	3
3	0	0	0	0	3	3	3	3
4	0	0	0	0	3	3	3	3
5	0	0	0	n/d	3	3	3	n/d
6	0	0	0	0	3	3	3	3
7	0	0	0	0	3	3	3	3
TOTAL	0	0	0	0	21	21	21	18

% Protection 100 100 100 100

$$\frac{(\text{Untreat} - \text{Treat})}{(\text{Untreat})}$$


 Terry A. Klein
 LTC, MS
 Manager, Malaria Section
 Division of CD & I

SCRD-UWF-B (1hh)

11 May 1994

MEMORANDUM FOR

Chief, Department of Entomology, Division of Communicable Disease
and Immunology, Walter Reed Army Institute of Research,
Washington, DC 20307-5100

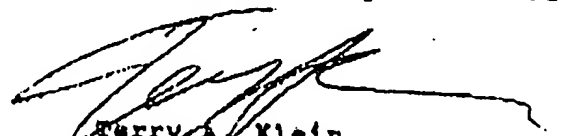
SUBJECT: Proposed modification of CRDA

1. We are currently evaluating Arthropod Repellent Sunscreen formulations in the laboratory (IguanaTM SPF 15, 20% deet and SPF 23, 35% deet, provided by Amon-Ré, Inc., P.O. Box 1657, Thomasville, GA 31792; TELE: 1-800-344-8262) against Aedes aegypti and Anopheles stephensi to determine efficacy and duration in the laboratory.
2. In preliminary evaluations, both repellents have been effective for up to 10-12 hours on male subjects. The SPF 15 cream has been effective for up to 6 hours on female subjects. Further evaluations are planned to be conducted to determine differences in the duration and requirements for application between males and females.
3. We are proposing to evaluate the SPF 15, 20% deet repellent/sunscreen cream in the field against day-biting insects and during the evening hours against malaria vectors. Potential areas of evaluation are listed below:
 - a. Australia, Anopheles farauti malaria vector and species of sand flies (Culicoides).
 - b. Peru, Culicoides sp., vectors of oropouche virus (day biters) and Anopheles sp. for malaria vectors.
 - c. Florida, Culicoides sp., nuisance biting flies.
 - d. Brazil, Black flies [vectors of onchocerciasis (river blindness)] and Anopheles sp., for malaria vectors.
4. Approximate costs for conducting field trials at one of the sites are estimated at approximately \$10,000.00. This includes travel, per diem and costs to conduct the studies. Advantages for overseas testing is that it utilizes local national volunteers or military units (less expensive) and will provide

information on insects that transmit diseases, i.e., malaria, leishmaniasis and arboviruses.

5. Data would be provided to Amon-Ré and published in refereed scientific journals (subsequent to review by Amon-Ré.

6. An amendment to the existing CRDA between Amon-Ré and WRAIR requesting 10K to conduct studies and a statement of work is being prepared by the Manager, Repellent Section, Department of Entomology, WRAIR.



Terry A. Klein
LTC, MS
Manager, Repellent Section
Division of CD&I

WHAT IS CLAIMED IS:**CLAIM 1**

A composition which functions as a sweet tasting sunscreen protectant and non-greasy, pleasant smelling insect repellent having an extremely long efficacy period when used by a person in rainy conditions and prolonged periods of high humidity as in tropical and sub-tropical rain forests comprising in combination:

a first constituent functioning as a sunscreen and constituting from about between 10% to 20% by weight of the composition;

a second constituent functioning as an insect repellent constituting about between 10% to 30% of the composition;

a third constituent functioning as a water based solvent constituting about between 27% to 37% by weight of the composition;

a fourth constituent functioning as a sweetener constituting about between 0.05% to 0.15% by weight of the composition;

a fifth constituent functioning as a pleasant scent material constituting about between .2% to .3% by weight of the composition; and

a sixth constituent functioning as a water-proofing agent constituting about between 2% to 4% by weight of the composition.

CLAIM 2

A method for formulating a composition which functions as a sunscreen protectant and insect repellent having an extremely long efficacy period when used by a person in rainy conditions and prolonged periods of high humidity as in tropical and sub-tropical rain forests comprising the steps of:

combining water and propylene glycol with propeller agitation in a first stainless steel kettle for forming an initial mixture, the kettle being large enough to hold an entire volume of the composition;

heating the initial mixture to 75° C;

slowly sifting in carbopol and then Pemulen TR1;

adding seamollient and disodium EDTA uniformly for forming an interim mixture;

maintaining the temperature of the interim mixture in the first kettle at 75° C for 30 minutes;

combining N,N-diethyltoluamide, cetearyl alcohol, octyl methoxycinnamate, octyl salicylate, peg-40 stearate,

oxybenzone, triccontonyl PVP, and vitamin E acetate with slow agitation for forming a second initial mixture in a second stainless steel kettle;

heating the second initial mixture to 85° C;

maintaining the temperature of the second initial mixture in the second kettle for 30 minutes;

adding the second initial mixture in the second kettle uniformly to the interim mixture in the first kettle for forming a second interim mixture;

mixing the second interim mixture in the first kettle for 30 minutes;

adding triethanolamine to the second interim mixture in the first kettle using slow sidesweep agitation for forming a third interim mixture;

mixing the third interim mixture in the first kettle for 30 minutes while maintaining the temperature at 75° C.

cooling the third interim mixture in the first kettle to 45° C while stirring slowly;

slowly adding citronella, fragrance, saccharin and germaben II to the third interim mixture in the first kettle for forming a resultant mixture;

mixing the resultant mixture in the first kettle for 20 minutes for providing uniformity;

passing the resultant mixture in the first kettle through a Gifford-Wood colloid mill with a narrow setting for providing a small particle size;

recirculating the resultant mixture in the first kettle until homogeneity is achieved; and

packaging the resultant mixture.

CLAIM 3

The composition as set forth in Claim 1 wherein the major component of the first constituent is benzophene-3.

CLAIM 4

The composition as set forth in Claim 1 wherein the principal component of the second constituent is N,N-Diethyl-m-Toluamide.

CLAIM 5

The composition as set forth in Claim 1 wherein the principal component of the third constituent is distilled water.

Claim 6

A composition as recited in Claim 1 wherein the principal component of the fourth constituent is sodium saccharin.

Claim 7

A composition as recited in Claim 1 wherein the principal components of the fifth constituent are citronella and fragrance MF 3871.

Claim 8

A method of applying a compound to an exposed portion of a person's body for functioning as a sunscreen protectant and insect repellent having an extremely long efficacy period when used by a person in rainy conditions and prolonged periods of high humidity as in tropical and sub-tropical rain forests, comprising the steps of:

providing a compound formed of a sunscreen protectant, an insect repellent, a water based solvent, a sweet tasting ingredient, and a pleasant smelling compound;

agitating the compound by shaking until the compound is homogenous; and

pouring the homogenous compound onto an applicator and then coating the exposed portions of the body with the homogenous compound.

Claim 9

A composition as recited in Claim 1 which forms a thin film when applied to the skin of the person for remaining on the skin when submerged under water for long periods of time of about between 1 to 1.25 hours.

Claim 10

A composition as recited in Claim 9 wherein the thin film formed on the skin of the person is non-greasy to the touch.

Claim 11

A composition as recited in Claim 9 which retains a SPF factor of 15 when submerged under water for long periods of time of about between 1 to 1.25 hours.

Claim 12

A composition as recited in Claim 1 wherein the sixth constituent is Tricontonyl PVP material.

Claim 13

A composition as recited in Claim 1 and further including a film forming ingredient (Ganex WP660) for forming a barrier between the second constituent and the sixth constituent for preventing the second constituent from dissolving the sixth constituent.

Claim 14

A composition as recited in Claim 1 and further including a seventh constituent for encapsulating and isolating the second constituent from the other remaining constituents.

Claim 15

A composition as recited in Claim 14 wherein the seventh constituent is a paraffin material, preferably petroleum wax.

Claim 16

A composition as recited in Claim 1 wherein the sixth constituent lowers the vapor pressure of the composition for increasing the efficacy of the composition over the entire range of percentage by weight of the second constituent.

Claim 17

A method as recited in Claim 2 and further including the steps of:

dissolving a non-cosmetic resin in the resultant mixture;

adding additional non-cosmetic resins for forming a resultant solid compound;

curing the resultant solid compound to a completely solid state;

grinding the resultant solid compound into a fine powder; and
impregnating another solid material for resisting insects when
the other solid material is used in another process.

Claim 18

A method as recited in Claim 17 and further including replacing
the step of impregnating another solid material for resisting
insects when the other solid material is used in another
process with the step of:

impregnating a second liquid material for resisting insects
when the second liquid material is used in another process.

Claim 19

A method for formulating a composition as recited in Claim 2
and further including the step of adding a paraffin wax for
encapsulating the N-N-diethyltoluamide immediately after the
step of maintaining the temperature of the interim mixture in
a first kettle at 75° C for thirty minutes.

Claim 20

A method for formulating a composition as recited in Claim 2
and further including the following steps immediately after
mixing the second interim mixture in the first kettle for 30
minutes;

dissolving a non-cosmetic resin in the resultant mixture;

adding additional non-cosmetic resins for forming a resultant solid compound;

curing the resultant solid compound to a completely solid state;

grinding the resultant solid compound into a fine powder; and

impregnating another solid material for resisting insects when the other solid material is used in another process.

Claim 21

A method for formulating a composition as recited in Claim 2 and further including the following steps immediately after mixing the second interim mixture in the first kettle for 30 minutes;

dissolving a non-cosmetic resin in the resultant mixture;

adding additional non-cosmetic resins for forming a resultant solid compound;

curing the resultant solid compound to a completely solid state;

grinding the resultant solid compound into a fine powder; and

impregnating another liquid material for resisting insects when the other liquid material is used in another process.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/13422

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61K 7/42

US CL :424/059

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/059

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
CAS ONLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A, 2,435,005 (HUPPKE ET AL) 27 January 1948, column 3, lines 44-70.	1-21
X,	US, A, 2,853,423 (LaVia) 23 SEPTEMBER 1958, column 2, lines 63-72.	1-21
X,	US,A, 3,821,363 (BLACK ET AL) 28 JUNE 1974, column 8, lines 1-39.	1-21
X	US,A, 4,477,467 (NISHIZAWA ET AL) 16 OCTOBER 1984, column 6, lines 16-30.	1-21
X	US,A, 2,356,801 (TRAVIS ET AL) 29 AUGUST 1944, column 1, lines 19-27.	1-21

☐

Further documents are listed in the continuation of Box C.

☐

See patent family annex.

- * Special categories of cited documents:
- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *G* document member of the same patent family

Date of the actual completion of the international search

08 MARCH 1995

Date of mailing of the international search report

17 MAR 1995

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

DALE R. ORE

Telephone No. (703) 308-1235